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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/826,627	04/16/2004	Teun Sleurink	TIMBERLAKE/AQTRITION	1299				
7723 PHILIP L BATEMAN P O BOX 1105 DECATUR, IL 62525	7590 07/02/2007		<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">RAMACHANDRAN, UMAMAHESWARI</td></tr></table>		EXAMINER		RAMACHANDRAN, UMAMAHESWARI	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,627	Applicant(s) SLEURINK, TEUN	
	Examiner Umamaheswari Ramachandran	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The examiner notes the receipt of the amendments and remarks received in the office on 5/21/2007. Claim 1 has been amended and claim 6 has been added new. Claims 1-6 are pending.

Response to Remarks

The rejection of claims 1-3 under 35 U.S.C. 102 is withdrawn due to the amendment of claim 1. Applicant's arguments filed 5/21/2007 regarding 35 U.S.C 103 rejection of claims 4-5 under 35 U.S.C. 103(a) as being unpatentable over Deuchler et al. (J. Dairy Sci, 81:238-242, 1998) in view of Irwin have been fully considered but they are not persuasive. Accordingly, the rejections of the claims 4-5 are being maintained. The amendment of claim 1 and further examination and search necessitated the new ground(s) of rejection presented in this Office action. The office action is made non-final.

Claim Rejections - 35 USC § 112(1)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1-6 are attributed to a method of feeding a non-encapsulated choline compound

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to a ruminant animal that enables most of the choline compound to bypass the rumen.

The specification does not provide any examples or case studies to describe the method of feeding choline compound to a ruminant animal that enables most of the choline compound or more than 50 percent of the choline compound as in claim 6.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the Invention:

All of the rejected claims are drawn to a method of feeding a choline compound that is non-encapsulated to a ruminant animal that enables most of the choline compound to bypass the rumen.

(2) Breadth of the claims:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims are drawn to a method of feeding a choline

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compound to a ruminant animal that enables most of the choline compound to bypass the rumen.

(3) Guidance of the Specification:

The guidance given by the specification a method of feeding a choline compound to a ruminant animal that enables most of the choline compound to bypass the rumen is minimal. There are no examples or case studies to show that most of the choline compound bypasses the rumen or more than 50% of the choline compound bypasses the rumen and reaches the abomasum without degradation.

(4) Working Examples:

The specification does not provide any case studies or examples to show that most of the choline compound or more than 50% of the choline compound bypasses the rumen and reaches the abomasum without degradation.

(6) The predictability of art:

The state of the art is such that it is not possible to predict that most of the choline compound or more than 50% of the choline compound bypasses the rumen and reaches the abomasums without degradation.

(7) The Quantity of Experimentation Necessary:

In order to practice the above claimed invention, one of skill in the art would have to first envision formulation, dosage, duration, route and an appropriate animal model system. One would then need to test the compound in the model system to determine whether or not most of the choline compound or more than 50% of the choline compound bypasses the rumen and reaches the abomasums without degradation. If

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unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding the method of feeding a choline compound that is non-encapsulated to a ruminant animal that enables most of the choline compound to bypass the rumen., one of skill in the art would have to envision a modification in the formulation, dosage, duration, route of administration etc. and appropriate animal model system, or envision an entirely new combination of the above and test the system again. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention of a method of feeding a choline compound that is non-encapsulated to a ruminant animal that enables most of the choline compound to bypass the rumen.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, a method of feeding a choline compound that is non-encapsulated to a ruminant animal that enables most of the choline compound to bypass the rumen is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghyczy (DE 10224240) in view of Irwin (<http://www.omafra.gov.on.ca/english/engineer/facts/86-053.htm>).and further in view of Deuchler et al. (J. Dairy Sci, 81:238-242, 1998).

Ghyczy teach an additive such as choline (5mg –2000 mg, 25-500 mg per kg of body weight of the animal) for feedstuff or drinking water for cattle, pigs, horses etc (see Abstract, col. 14, claim 25, translation has been requested). For example, if a cow weighs 500 kg, the amount of choline given would be 25 g and this amount falls within the range of the cited claim 2.

The method does not teach the amount of water to show that it is sufficient quantity to provide an effective amount of choline to the ruminant animal and the concentration of the choline compound.

Irwin teaches that milking cows drink about 85 kg of water per day (p 3, lines 13-20), and beef cattle 18-82 liters based on the weight (p 2, table 1). The reference further teaches that constant supply of water is one of the most essential needs in a livestock feeding program and the daily water requirements of livestock vary with air temperature, air humidity, species of animal, water content of the diet, loss of sweat due to exertion, temperature of the water and the salinity of the supply (p1, lines 1-7). For example, if the amount of choline administered is 25 g in 85 kg of water the concentration of choline compound is 0.03%.

The references do not teach the choline compound as choline chloride.

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Deuchler et al. teaches choline chloride as a dietary supplement and further teaches a method of administering 25, 20, 60 g, 75 g/day of choline chloride in 2 liters of water in the abomasum (p 239, experiment 1, experiment 2) of dairy cows.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add choline in 80-120 liters of drinking water in a method of feeding ruminant animals. Irwin teaches that milking cows drink about 85 kg of water per day and the daily water requirements of livestock vary with air temperature, air humidity, species of animal, water content of the diet, loss of sweat due to exertion, temperature of the water and the salinity of the supply. Hence one of ordinary skill in the art would have been motivated to feed 85-120 liters of drinking waters to cow to keep up with the daily water requirements of livestock as taught by Irwin. One of ordinary skill in the art would have been motivated to add choline chloride for choline in the drinking water of livestock because it is a salt of choline compound and Deuchler et al. teaches the safety of choline chloride and the benefit as a dietary supplement to the livestock.

Response to Arguments

Applicants' argue that Irwin article concerns drinking water, but does not mention choline. In response, Irwin reference has been used to show the amount of drinking water consumed by the cows in general. Deuchler teaches the administration of choline compound dissolved in water in the abomasum indicating that degradation takes place in the rumen and it would have been obvious to one of ordinary skill in the art from his teachings to administer choline compound to bypass rumen to avoid the degradation of the supplement.

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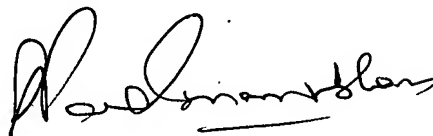
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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SUPERVISORY PATENT EXAMINER